

INFORMED CONSENT FOR LASER REFRACTIVE EYE SURGERY

LASER IN-SITU KERATOMILEUSIS (LASIK) and PHOTOREFRACTIVE KERATECTOMY (PRK)

INTRODUCTION

This information is being provided to you so that you can make an informed decision about LASIK and PRK as surgical options to reduce or eliminate your need for glasses and/or contact lenses. Both LASIK and PRK are irreversible surgical procedures which use the excimer laser to treat a range of nearsightedness (myopia), farsightedness (hyperopia), and astigmatism by removing corneal tissue and changing the overall shape of the cornea. PRK surgery is performed by applying the laser to the surface of the cornea after removal of the superficial skin cell layer (epithelium). LASIK surgery is performed by creating a partial-thickness, hinged corneal flap with a femtosecond laser or a device known as a microkeratome, lifting the flap, and applying the laser to the exposed corneal tissue. The flap is then replaced to its original position.

LASIK and PRK are elective procedures: there is no emergency condition or other reason that requires or demands that you have it performed. You could continue wearing contact lenses or glasses and have adequate visual acuity. This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur. It is possible that surgery may make your vision worse.

ALTERNATIVES TO LASIK and PRK

If you decide not to have LASIK or PRK, there are other methods of correcting your nearsightedness, farsightedness, or astigmatism. These alternatives include, among others, eyeglasses, contact lenses, and other refractive surgical procedures.

PATIENT CONSENT

In giving my permission for LASIK or PRK, I understand the following: The purpose of performing LASIK or PRK is to decrease my overall dependence on corrective lenses (glasses or contacts), not to completely eliminate their need or use. No surgical procedure is perfect and vision after surgery is not expected to be perfect without corrective lenses. Corrective lenses may be needed for best vision after surgery. LASIK and PRK do not prevent or correct the natural aging process of the eyes called presbyopia, which causes people with normal vision to become more and more dependent on reading glasses as they get older. At some point, usually in my early to mid 40s, I will likely need reading glasses to see clearly up close, though this may occur at an earlier age. The long-term risks and effects of LASIK and PRK are unknown. I have received no guarantee as to the success of my particular case. I understand that the following risks are associated with the procedures:

VISION THREATENING COMPLICATIONS

1. I understand that the femtosecond laser, microkeratome, or the excimer laser could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss.
2. I understand that, in using the femtosecond laser or microkeratome for LASIK, instead of making a flap, an entire portion of the central cornea could be cut off, and very rarely could be lost. If preserved, I understand that my doctor would put this tissue back on the eye after the laser treatment. It is also possible that the flap incision could result in an incomplete flap, irregular flap, decentered flap, or a flap

that is too thin. If this happens, it is likely that the laser part of the procedure will have to be postponed until the cornea has a chance to heal sufficiently to try to create the flap again, usually 4-6 months later.

3. I understand that, in using the femtosecond laser or microkeratome for LASIK, a superficial corneal abrasion (epithelial defect) could result in approximately 5% of patients. This may necessitate the placement of a bandage soft contact lens until the defect has healed, and I understand that I would require more intensive topical (and possibly oral) steroid medication treatment in an effort to reduce the risk of diffuse lamellar keratitis (DLK), which may become visually significant due to corneal scarring, irregular astigmatism, and corneal melting.
4. I understand that, following LASIK, the superficial skin cell layer (epithelium) may grow and proliferate in the space between the corneal flap and the cornea. This may happen days, weeks, or even months following LASIK. If progressive, this may lead to corneal flap swelling and decompensation, irregular astigmatism, loss of vision, and the need for further surgery, to include lifting of the flap with removal of the epithelial ingrowth.
5. I understand that irregular healing of the LASIK flap, or wrinkles (striae) in the corneal flap, could result in a distorted cornea. This would mean that glasses or contact lenses may not correct my vision to the level possible before LASIK. If this distortion in vision is severe, additional surgery may be needed, possibly including a partial or complete corneal transplant.
6. I understand that it is possible a perforation of the cornea could occur during LASIK, causing complications, including loss of some or all of my vision. This could also be caused by an internal or external eye infection that could not be controlled with antibiotics or other means.
7. I understand that mild or severe infection is possible following either LASIK or PRK. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation or even loss of the eye.
8. I understand that scar tissue ("haze") can form on the surface of the cornea following PRK surgery which may cause loss of vision in severe cases, distortion of vision, and nighttime visual complaints. I understand that all patients are at risk of haze formation, and that the risk is proportional to the degree of nearsightedness or farsightedness treated with the laser. I understand that the risk of haze formation can be minimized to a certain degree by wearing protective sunglasses while outdoors for six or more months following surgery, and by using topical steroid eye medications as instructed. Visually significant scar formation is also possible, though less common, with LASIK surgery.
9. I understand that topical steroid eye medications are routinely prescribed following LASIK and PRK, and that these medications have rare, but potentially significant, side effects to include cataract formation, intraocular pressure elevation with potential for optic nerve damage (glaucoma), and increased risk of infection. I understand the importance of attending all of my scheduled post-operative appointments so that I can be evaluated for any of these possible side effects.
10. I understand that other very rare complications threatening vision include, but are not limited to, corneal swelling, progressive corneal thinning (ectasia), appearance of "floaters," retinal detachment, bleeding in the eye, venous and arterial blockage, glaucoma, cataract formation, total blindness, and even loss of my eye.

NON-VISION THREATENING SIDE EFFECTS

1. Blurriness is common in the healing process following LASIK and PRK. It generally takes 7 to 10 days to clear, however it may take longer. My visual acuity will generally be stable by one month post-operatively, although full stability and recovery may take 4 to 6 months or longer, especially for PRK.
2. I understand that there may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. I understand these conditions usually occur during the normal stabilization period of from one to three months, but they may also be permanent.
3. Following LASIK and PRK, there is expected discomfort or pain, the feeling of something in the eye, tearing, swelling of the eyelids, and redness of the eye. These are associated with the normal post-treatment healing process, and should be expected to last from 1-2 days with LASIK, and 4-6 days with PRK, though it may last longer. Bruising and redness of the eye may last for several weeks.
4. I understand there may be a decrease in contrast sensitivity, or a decrease in the overall sharpness and quality of vision, despite good visual acuity. This usually resolves with time, but may be permanent.
5. I understand that there is an increased risk of eye irritation related to drying of the corneal surface, especially following LASIK. These symptoms may last for 6-12 months or, on rare occasions, be permanent. Artificial tear use will be necessary for several months after surgery. Other treatment, including closure of the eyelid tear drainage ducts, may be needed.
6. I understand that an overcorrection or undercorrection could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. I understand an overcorrection or undercorrection is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.
7. I understand that at night there may be a "starbursting" or halo effect around lights. I understand that this condition usually diminishes with time, but could be permanent. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night. I understand that I should not drive until my vision is adequate both during the day and at night.
8. I understand that I may not get a full correction from my LASIK or PRK procedure and this may require future enhancement procedures, such as more laser treatment or the use of glasses or contact lenses.
9. I understand that there may be a "balance" problem between my two eyes after LASIK or PRK has been performed on one eye, but not the other or if there is an unusual healing response in one eye after bilateral surgery. This phenomenon is called anisometropia. I understand this may cause eyestrain and make judging distance or depth perception more difficult.
10. I understand that, after PRK or LASIK, the eye may be more fragile to trauma from impact. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.
11. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.
12. I understand that, following PRK, a bandage soft-contact lens will be placed on the eye where it will remain for 4-5 days, or until the epithelium has healed. I understand that this is not an FDA-approved use of the contact lens, and that it slightly increases the risks of infection. I understand the contact lens is

placed to decrease post-operative discomfort and improve healing. Should the contact lens fall out of the eye, there will be an expected increase in pain.

13. I understand that visual acuity I initially gain from LASIK or PRK could regress, and that my vision may go partially back to a level that may require glasses or contact lens use to see clearly.
14. I understand that the correction that I can expect to gain from LASIK or PRK may not be perfect. I understand that it is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of my life. I understand I may need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.
15. I understand that I must not drive the day of surgery and not until I am certain that my vision is adequate for driving. I understand that I must not drive while taking narcotic pain medications or sedatives, or for at least 24 hours following the last dose of these medications.
16. I understand that if I currently need reading glasses, I will still likely need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have this surgery.
17. Even 90% clarity of vision is still slightly blurry. Enhancement surgeries can be performed when vision is stable unless it is unwise or unsafe. In order to perform an enhancement surgery, there must be adequate tissue remaining. If there is inadequate tissue, it may not be possible to perform an enhancement. An assessment and consultation will be held with the surgeon at which time the benefits and risks of an enhancement surgery will be discussed.
18. I understand that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body. I understand that, since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.
19. I understand that certain eye conditions, systemic medical conditions, or medication use may make LASIK and/or PRK less safe or predictable. Medical conditions such as vascular disease, diabetes, autoimmune disease, keloid formation, or immunocompromised states; eye conditions such as keratoconus, irregular astigmatism, thin corneas, history of herpes simplex keratitis, cataract, or glaucoma; and medication use, such as Acutaine, Amiodorone, or Sumatriptan (Imitrex) may significantly affect my response to surgery. It is extremely important that I fully disclose my medical history and medication use and discuss any chronic medical or ocular conditions and any medication use with my eye doctor.
20. I understand that it is not possible to state every complication that may occur as a result of LASIK or PRK surgery. I also understand that complications or a poor outcome may manifest weeks, months or even years after LASIK or PRK surgery

OFF-LABEL USE OF MEDICINE AND MEDICAL DEVICES: I understand that many things involved with refractive surgery are considered off-label uses of medicine and medical devices. All medications and devices used have been approved for medical use by the FDA. However, some of these devices and medications were FDA approved for only specific types of treatment. Use of these devices and medications for other types of treatment is legal, but considered “off label.” Medications and devices that we use in an off label fashion include, but are not limited to, using the excimer laser for PRK, use of mitomycin-C in PRK, use of post-operative antibiotics, and use of bandage soft contact lenses. While these medicines and devices have not been approved by

the FDA for these particular uses, they are widely used in ophthalmology for PRK and LASIK and are considered accepted practices.

FOR WOMEN ONLY: I am not pregnant or nursing, and have not been pregnant or nursing within the past six months. I understand that pregnancy or nursing could adversely affect my treatment results. I also understand that I should not become pregnant while taking steroid eye drops post-operatively, which may last up to three months after surgery.

FOR PRESBYOPIC PATIENTS: (patients 40 years or older or patients requiring a separate prescription or bifocals for reading): The option of monovision has been discussed with my ophthalmologist.

SPECIAL MILITARY CONSIDERATIONS:

1. Smallpox vaccine: I understand that LASIK or PRK should not be performed on an individual within a minimum of three weeks after smallpox vaccination. I also understand that individuals who are currently taking topical steroid eye drops following LASIK or PRK should not receive the smallpox vaccine until their steroid course is completed.
2. I understand that LASIK is disqualifying for attending USASOC-sponsored schools such as HALO, SCUBA, Special Forces Qualification course, SERE, and certain ARSOF units. PRK is allowed for Special Operations personnel, and LASIK may be available if granted a waiver obtained through the appropriate command. Soldiers who are interested in Special Operations should NOT undergo LASIK treatment for any reason unless a waiver is granted. I also understand that PRK and LASIK are disqualifying for flight status and requires a waiver to return to flight status. Personnel on flight status or receiving flight pay should consult with their flight surgeon prior to having PRK or LASIK. A waiver may not be possible after surgery, which could lead to loss of flight status and flight pay. I also understand that the surgery may disqualify me from commissioning or certain occupations such as aviation.
3. I understand that if my vision after surgery should fall outside the minimum acceptable for my job that I may be required to change my rate/designation, and that I may be referred for a medical evaluation board. As this is considered elective surgery, should I be separated from the service due to any complication that results from my surgery, I understand that I may not receive benefits related to the surgery.
4. If I suffer any injury directly related to my surgery, immediate medical attention is available at the nearest military medical treatment facility, if needed. I understand that although no financial compensation is available, any injury resulting from my surgery will be evaluated and treated in keeping with the benefits of care to which I am entitled under applicable Army, other Department of Defense, and other state or federal regulations.
5. I understand that it is my responsibility to ensure that PRK or LASIK has been approved for me by my commanding officer and that I will meet all the specific requirements for my military service community. The Tripler Warfighter Refractive Surgery Center will do its best to ensure I meet medical standards for my community, but it will be up to my specific service community whether or not I meet medical standards to continue in my profession or to pursue specific training or career opportunities. "They didn't tell me it would be disqualifying" will not be an acceptable excuse if my surgery disqualifies me for a particular service community or specialty.

Mitomycin-C: All patients who elect to undergo PRK on their eye(s) have been informed that they are at some risk for scar (haze) development and that the risk is proportional to the depth of corneal tissue ablation and therefore to the degree of nearsightedness and astigmatism treated. In other words, the higher the amount of pre-operative nearsightedness without astigmatism, the higher risk of developing significant post-operative "haze."

Scar or haze may also be more likely if there are pre-existing corneal scars or if the eye has had previous trauma or surgery. The use of prophylactic Mitomycin-C in an effort to prevent or minimize the formation of “haze” may be recommended by my surgeon to decrease the risk of haze formation.

Though considered an off-label use (see above), Mitomycin-C has been used for decades in Ophthalmology surgeries with very positive outcomes. There are potential well-known, though very rare, visually-significant side-effects and complications that may take years to develop. These have been felt to be due to late ischemic affects (damage to blood vessels) to the sclera and the conjunctiva and have resulted in delayed healing, scleral melts, and perforations. Possible complications of using Mitomycin-C for PRK include delayed healing and corneal thinning or “melting.” However, these complications are extremely rare in PRK, as a very dilute solution of Mitomycin-C is used and it is in contact with the cornea (which contains no blood vessels) for only a short period of time. The use of Mitomycin-C does not guarantee that “haze” will not develop.

I give my consent to the use of Mitomycin-C to decrease the risk of scar formation, as determined by my eye surgeon.

PROTECTED HEALTH INFORMATION (PHI) AND HIPAA: Patient information will be entered into an encrypted data base called “SurgiVision®.” Protected Health Information (PHI) is encrypted prior to every electronic data transmission; PHI is stored in an encrypted data file format. Data that’s collected will be entered into the database and stored in an encrypted, de-identified data file format. Patients’ identity and personal contact information will never be disclosed to any third party agencies. Collected data may be used for purposes that are unrelated to their care, including but not limited to: research, scientific and clinical symposiums, meetings, publication(s), peer-to-peer consultations, and marketing. Alcon Laboratories, INC., SurgiVision®, and other third parties will be given access to the de-identified clinical information. Tripler Army Medical Center Warrior Refractive Surgery Clinic complies with all **The Health Insurance Portability and Accountability Act of 1996 (HIPAA)** and Federal Privacy Regulations

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of the procedure known as LASIK and PRK have been presented to me in detail in this document and explained to me by my doctor. My doctor has answered all my questions to my satisfaction. I therefore consent to LASIK and/or PRK surgery, as indicated.

I give my permission for my ophthalmologist to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. I also give my permission for my ophthalmologist to use data about my procedure and subsequent treatment to further understand LASIK and PRK. I understand that representatives from the healthcare industry may be present in the treatment room during my surgery.

FOR WOMEN ONLY: I am not pregnant or nursing and I will not become pregnant for at least 3 months after my surgery. I understand that I may be asked to have a pregnancy test performed.

(patient initials)_____/Date_____

(Please **INITIAL** the appropriate type of surgery and **INITIAL** which eye(s) are to be treated.)

I HAVE ELECTED TO UNDERGO AND GIVE PERMISSION FOR: ____LASIK ____PRK

IF FOR ANY REASON WE ARE UNABLE TO PERFORM LASIK, I GIVE MY CONSENT TO PROCEED WITH PRK AS APPROPRIATE. (patient initials)_____/Date_____

EYE(S) TO BE TREATED: ____Both (OU) ____Right Eye (OD) ____Left Eye (OS)

Patient Signature

Date

Patient Name (Print)

Date of Birth:_____

Witness Signature

Date

Witness Name (Print)

Physician Signature

Date

Physician Name (Print)

I have been offered a copy of this consent form (patient initials)_____